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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/186,903 11/03/98 BLASCHUK

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000500 HY22/0702  
SEED INTELLECTUAL PROPERTY LAW GROUP PLL  
701 FIFTH AVE  
SUITE 6300  
SEATTLE WA 98104-7092

EXAMINER

DECLoux, A

ART UNIT

PAPER NUMBER

1644

*16*

DATE MAILED:

07/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Advisory Action

Application No.  
09/185,908

Applicant(s)

Blaschuck et al

Examiner

DeCloux, Amy

Art Unit

1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

THE REPLY FILED Jun 4, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

## THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

4. ☒ Applicant's reply <sup>would</sup> ~~has~~ overcome the following rejection(s):  
The 112 first new matter rejection and the 112 2nd rejection.
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 2-4, 6-8, 11-13, 27-43, 46-49, 52-55, and 58-61
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☒ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☒ Other: U.S. Patent No. 5,981,478 on attached PTO 892

### DETAILED ACTION

1. Applicant's after-final amendment, filed 6-4-2001 (Paper No. 15), is acknowledged.
2. Applicant's election of Group I, claims 1-20, 27-43, 46-49, 52-55 and 58-61 in Paper No. 10, mailed April 10, 2000, and the species WKIYSYAG (SEQ ID NO:34) as the specific species to which the claims may be restricted if no generic claim is held allowable.
3. Claims 9-10, and 14-20 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.
4. The rejections of record can be found in the previous Office Actions mailed 6/30/00 (Paper No. 11) and 3/27/01 (Paper No. 15).

In view of applicant's after-final amendment, filed 6-4-2001 (Paper No. 15), the 112 2nd rejection and the 112 first new matter rejection has been withdrawn; however, the 112 first enablement and written description rejections, the 102(b) rejection anticipated by Bult, have been maintained.

As reiterated in the previous office action mailed 3/27/01 (Paper No. 15), the 102(b) rejection anticipated by Ruoslahti et al (U.S. Patent No. 5,627,263) has been withdrawn. Applicants point out that the sequence CRGDSFVGC is not taught by said patent and the examiner agrees. Said sequence is actually taught by Ruoslahti et al in U.S. Patent No. 5,981,478 (Table No.3) which if applied would be a 102(e) rejection.

Applicants traverse the 102(b) rejection anticipated by Bult, on the grounds that the nucleotide sequence does not contain the information as to the frame in which the nucleotide sequence is translated. However the examiner's submission of the cDNA sequence in the previous Office Action mailed 3/27/01 (Paper No. 15) does indicate the reading frame of said nucleotide sequence. Therefore though applicant's arguments have been carefully considered, said rejection is maintained, essentially for the reasons of record.

Applicant's traverse the 112 first enablement rejection on the grounds that a "claudin CAR sequence" is defined in the specification as an amino acid sequence present within a naturally occurring claudin and capable of modulating a claudin mediated function. However, as indicated in the previous Office Action mailed 3/27/01 (Paper No. 15), ~~However~~, the more unpredictable an area is, the more enablement is

required. That this area is unpredictable is evidenced by generation by applicant of this deduced consensus amino acid sequence for a claudin CAR sequence (SEQ ID NO:1), based on a sequence homology alignment of the amino acid sequences of extracellular domain one of representative mammalian claudins as indicated in Figure 1 of the instant specification. In view of the fact that there is no clear guidance from Applicant's specification that an agent comprising SEQ ID NO:1 is capable of modulating claudin-mediated processes, such as cell adhesion, especially when applicant has not disclosed the sequence identity of CAR containing peptides that actually reduce cell adhesion in the disclosed example, nor the 9 amino acid CAR sequence used to make the antibodies that have cell adhesion modulating activity as disclosed in Examples 2 and 4. The only proposed uses for the an agent comprising the claimed CAR sequence are based upon an alignment with other mammalian claudins, and there is no predictability that this small sequence identity (or which part(s) thereof) would confer the biological activities including modulating claudin-mediated processes, such as cell adhesion, to an agent comprising the claimed CAR sequence (SEQ ID NO:1) because Applicant has not disclosed where the biological activity of cell adhesion of the claudin resides within the (SEQ ID NO:1) and if this consensus sequence alone is sufficient. Therefore, though applicant's arguments have been carefully considered, said rejection is maintained.

Applicants traverse the 112 first written description on the grounds that their specification would allow one of ordinary skill in the art the ability to distinguish claudin sequences from those that are not, and assert that the definition of a claudin CAR sequence as comprising a 22KD integral membrane protein with two extracellular and four transmembrane domains which display at least 30% sequence identity to a member of the claudin family. However as stated in the previous office action mailed 3/27/01 (Paper No. 15), applicant has not addressed the inadequate description of a claudin CAR sequence, specifically what sets apart claudin sequences as a genus from sequences which are not claudin sequences, as noted in the last few sentences of this written description rejection described in section 4 of the office action mailed 6/30/00 (Paper No. 11). Therefore, though applicant's arguments have been carefully considered, said rejection is maintained.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600

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receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner  
Group 1640, Technology Center 1600  
June 28, 2001

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182 1644